Adopt 17 Cal. Code of Regs. section 100060 to read:

§ 100060. SCRO Committee Membership and Function.

(a) A SCRO committee shall be comprised of persons with expertise in, including but not limited to, developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical issues in stem cell research. A SCRO committee shall include at least one non-scientist member of the public who is not employed by, or appointed to, or remunerated by the relevant research institution and who is not part of the immediate family of a person who is affiliated with the institution. In addition, a SCRO committee shall include at least one patient advocate. Any member of a SCRO committee member may be reimbursed ~~for permissible expenses, as defined in Title 17, California Code of Regulations, section 100020, subdivision (h)~~for reasonable out-of-pocket expenses for attending the meeting, not including lost wages. ~~In addition, a SCRO committee shall include at least one patient advocate.~~ No SCRO committee may have a member participate in the SCRO committee's initial or continuing review of any project in which the member has a ~~professional or financial stake~~ a conflicting ~~of~~ interest, except to provide information to the SCRO committee ~~IRB~~.

(b) The designated SCRO committee shall provide scientific and ethical review of CIRM-funded research consistent with the requirements of Section 100070 and other applicable CIRM requirements.

(c) The SCRO committee shall facilitate education of investigators with applicable requirements of this chapter.

(d) A SCRO committee may provide oversight for two or more funded research institutions, provided the SCRO committee has oversight authority consistent with the

requirements of this chapter.

(e) A SCRO committee may be convened by an institution, a group of institutions, the CIRM or other state agency.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100070 to read:

§ 100070. SCRO Committee Review and Notification.

(a) CIRM-funded research involving the procurement or use of human oocytes may not commence without SCRO committee review and approval in writing. For such SCRO committee review and approval, ~~the~~ a member of the committee with expertise in assisted reproduction shall be present. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (a)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to use oocytes including a justification for the number needed. If SCNT is proposed a justification for SCNT shall be provided.

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

(b) CIRM-funded research involving use of human embryos may not commence without SCRO committee review and approval in writing. ~~For such SCRO committee review and approval, the member of the committee with expertise in assisted reproduction shall be present.~~ The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (b)(3) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the

investigator to:

(1) Provide an acceptable scientific rationale for the need to use embryos including a justification for the number needed.

(2) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(3) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Animal Care and Use Committee (IACUC), Institutional Bioethics Committee (IBC), or other mandated review.

(c) CIRM-funded research with the aim to derive or create a covered stem cell line may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (c)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific rationale for the need to derive a covered stem cell line.

(2) If SCNT is proposed as a route to generating human stem cell lines, a justification for SCNT shall be provided.

(3) Demonstrate experience, expertise or training in derivation or culture of human or nonhuman stem cell lines.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, Institutional Bioethics Committee (IBC), or other mandated review.

(5) Document how stem cell lines will be characterized, validated, stored, and distributed to ensure that the confidentiality of the donor(s) is protected.

(d) CIRM-funded purely in vitro research utilizing covered stem cell lines may not commence without written notification to the designated SCRO committee. At a minimum, the notification shall:

(1) Provide assurance that all covered stem cell lines have been acceptably derived.

(2) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(e) CIRM-funded research introducing covered stem cell lines into non-human animals or introducing neural-progenitor cells into the brain of non-human animals at any state of embryonic, fetal, or postnatal development may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (e)(3) of this regulation as a condition of granting its approval. The SCRO committee may establish guidelines and procedures for expedited review of animal research so that review by the entire SCRO committee is not required. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific for rationale for introducing stem cells into non-human animals.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the nonhuman animal tissues.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(f) CIRM-funded research introducing stem cells from covered stem cell lines into a live born human may not commence without SCRO committee review and approval in writing. The designated SCRO committee may require that modification be made to proposed research or documentation of compliance with the requirements of subdivision (f)(4) of this regulation as a condition of granting its approval. At a minimum, the SCRO committee shall require the investigator to:

(1) Provide an acceptable scientific for rationale introducing stem cells into humans.

(2) Provide assurance that all covered stem cell lines have been acceptably derived.

(3) Evaluate the probable pattern and effects of differentiation and integration of the human cells into the human tissues.

(4) Provide documentation of compliance with any required review of the proposed research by an IRB, IACUC, IBC, or other mandated review.

(g) ~~Investigators are entitled to reconsideration of a SCRO committee decision. Requests must be made in writing and include a summary of the basis for the reconsideration. Investigators are entitled to be present in order to provide information and responses during the reconsideration.~~ In cases where SCRO committee approval is required, a SCRO committee shall

notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure SCRO committee approval of the research activity. If the SCRO committee decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(h) SCRO committee approvals shall be reviewed no less frequently than once per year. The renewal review shall confirm compliance with all applicable rules and regulations. The SCRO committee may establish guidelines and procedures for expedited review of renewals so that review by the entire SCRO committee is not required.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.40, 124290.55, Health and Safety Code.

§ 100095. Additional Requirements for CIRM-Funded Research Involving Oocytes.

When procurement of oocytes are required for derivation CIRM-funded research, the SCRO committee must confirm the following conditions have been met:

(a) The clinic performing oocyte retrieval is a member of the Society for Assisted Reproductive Technology.

~~(b) For a woman providing oocytes for research and clinical infertility treatment (either for herself or another woman), the disposition of such oocytes shall not knowingly compromise the optimal reproductive success of the woman in infertility treatment.~~

~~(1) A woman providing oocytes for her own reproductive uses may not donate any eggs to research unless she has determined that she does not want or need them to optimize her own chances for reproductive success.~~

~~(2) A woman providing oocytes for donation to another person's reproductive efforts may not donate any of these eggs to research unless (a) the donation is expressly permitted by the recipient who is receiving her oocytes for reproduction and (b) her donation of oocytes for research is done without valuable consideration.~~

(b) For oocytes provided for reproductive uses, either for use by the donor or another woman, the disposition of oocytes shall not knowingly compromise the optimal reproductive success of the woman in infertility treatment.

(1) Oocytes provided by a woman for her own reproductive uses may not be donated to research unless (a) the woman has determined that she does not want or need them for her own reproductive success, and (b) the donation of oocytes for research is done without valuable consideration.

(2) Oocytes provided by a donor for a recipient's reproductive use may not be donated to research unless: (a) the donation is expressly permitted by the oocyte donor; (b) the recipient has determined that she does not want or need them for her own reproductive success; and (c) the donation of oocytes for research is done without valuable consideration.

(c) The CIRM-funded institution shall develop procedures to ensure that an individual who donates oocytes for CIRM-funded research has access to medical care at no cost to the donor that is required as a direct and proximate result of that donation ~~at no cost to the donor~~. If a donor is medically insured, the donor shall not be required to claim any treatment costs through her own insurance policy.

(d) The physician attending to any donor and the principal investigator shall not be the same person unless exceptional circumstances exist and an IRB has approved an exemption from this requirement.

(e) The physician performing oocyte retrieval shall not have a financial interest in the outcome of the research.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40, 124290.55, Health and Safety Code.

Adopt 17 Cal. Code of Regs. section 100100 to read:

§ 100100. Informed Consent Requirements.

(a) All CIRM-funded human subjects research shall be performed in accordance with Title 45 Code of Federal Regulations, Part 46 (Protection of Human Subjects), revised June 23, 2005, and California Health and Safety Code section 24173. In accordance with existing law, California Health and Safety Code section 24173 does not apply to a person who is conducting research as an investigator within an institution that holds an assurance with the United States Department of Health and Human Services pursuant to Title 45 Code of Federal Regulations Part 46, revised June 23, 2005, and who obtains informed consent in the method and manner required by those regulations.

(b) In addition to the requirements of 17 California Code of Regulations Section 100080, the following provisions apply when CIRM funded research involves donation of gametes, embryos, somatic cells or human tissue or derivation of new covered stem cell lines which donation or derivation occurs after the effective date of this Chapter:

(1~~b~~) CIRM-funds may not be used for research that violates the documented preferences of donors with regard to the use of their donated materials. The SCRO committee or IRB must confirm that donors of gametes, embryos, somatic cells or human tissue to be used to derive stem cell lines have given voluntary and informed consent in accordance with this section. To ensure donors are fully informed of the potential uses of donated materials, researchers shall disclose, in addition to the general requirements for obtaining informed consent identified in subdivision (a) of this regulation, all of the following, unless a specific item has been determined by the SCRO committee or IRB to be inapplicable.

(A~~1~~) Derived cells or cell products may be kept for many years.

(B~~2~~) Whether the identity(ies) of the donor(s) will be ascertainable to those who work with the resulting cells or cell products. If the identity(ies) of the donor(s) are retained (even coded), CIRM-funded researchers must discuss any plans for recontact of donors of materials used to derive cell lines and obtain consent for recontact. This requirement includes both recontacting donors to provide information about research findings and ~~recontacting donors~~ to ask for additional health information. ~~Donors may be~~ Recontact ~~in the future only~~may only occur if ~~they~~ the donor consents ~~to recontact~~ at the time of donation.

(C~~3~~) Researchers may use cell lines for future studies, some of which may not be predictable at this time.

(D~~4~~) Derived cells or cell products may be used in research involving genetic manipulation.

(E~~5~~) Derived cells or cell products may be transplanted into humans or animals.

(F~~6~~) Derived cells or cell products are not intended to provide direct medical benefit to the donor(s), except in the case of autologous donation.

(G~~7~~) The donation is being made without restriction regarding who may be the recipient of transplanted cells, except in the case of autologous donations.

(H~~8~~) That neither consenting nor refusing to donate materials for research will affect the quality of any future care provided to potential donors.

(9l) That the results of research may be patentable or have commercial potential, and that the donor will not receive patent rights and will not receive financial or any other benefits from future commercial development.

(2e) Researchers shall offer donors an opportunity to document their preferences regarding future uses of their donated materials. Researchers may choose to use materials only from donors who agree to all future uses.

(3d) For CIRM-funded research involving the donation of oocytes, the following additional requirements apply:

(A1) The description of foreseeable risk shall include but not be limited to information regarding the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia and pregnancy.

(B2) The physician must disclose his or her relationship to the research or researcher(s) to the egg donor.

~~(3) Prospective donors shall be informed of their option to deliberate before deciding whether or not to give consent. If a deliberation period is chosen, the researchers may not re-contact the prospective donor about the consent decision.~~

(C3) Prospective donors shall be informed of their option to deliberate before deciding whether or not to give consent. If a deliberation period is chosen, the donor shall be informed of their right to determine the method of recontact. The donor must be informed that they have the option to initiate recontact. The investigators shall not initiate recontact unless the donor has consented, and this consent is documented in the research record.

(D4) The researcher shall ascertain that the donor has understood the essential aspects of the research, following a process approved by the designated IRB or SCRO committee. Understanding the essential aspects of the research includes understanding at least that:

(iA) Their eggs will not be used for reproductive purposes.

(iiB) There are medical risks in oocyte donation, including the risks of ovarian hyperstimulation syndrome, bleeding, infection, anesthesia, and pregnancy.

(iiiC) The research will not benefit them or any other individuals directly at this time.

(ivD) Whether stem cell lines will be derived from their oocytes through fertilization, SCNT, parthenogenesis, or some other method.

(vE) Stem cell lines developed from their oocytes will be grown in the lab and shared with other researchers for studies in the future.

(viF) If stem cells are to be transplanted into patients, researchers might recontact the donor to get additional health information.

(viiG) Donors receive no payment beyond reimbursement for permissible expenses.

(viiiH) Stem cell lines derived as a result of their oocyte donation may be patented or commercialized, but donors will not share in patent rights or in any revenue or profit from the patents.

(5e) For CIRM-funded research involving the donation and destruction of embryos for stem cell research, the informed consent process shall include a statement that embryos will be destroyed in the process of deriving embryonic stem cells.

~~(f) For CIRM-funded research that uses umbilical cord, cord blood or the placenta for autologous donation or for purposes other than derivation of covered stem cell lines, consent shall be obtained from the woman giving birth. For CIRM-funded research that uses umbilical cord, cord blood or the placenta to derive covered stem cell lines for purposes other than autologous donation, in order to assure scientific rigor, consent shall be obtained from each legal parent, guardian and genetic parent. Nothing in this section shall be construed to affect state or federal law with regard to consent in reproductive decision making.~~

~~(g) For purposes of this regulation, "genetic parent" means the person who provided the sperm or ovum for fertilization.~~

(6) For CIRM-funded research that uses the umbilical cord, cord blood or the placenta, consent shall be obtained from the birth mother.

(7~~h~~) For CIRM-funded research involving the donation of somatic cells for SCNT, informed consent shall include a statement as to whether the donated cells may be available for autologous treatment in the future.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40, subd.(j), Health and Safety Code.

Reference: Sections 24173, 125290.35, 125290.40, 124290.55, 125315, Health and Safety Code.